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# United States Senate

WASHINGTON, DC 20510

March 25, 2011

Dr. Donald Berwick  
Director  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert Humphrey Building, Room 314  
Washington, DC 20201

Dear Director Berwick:

I am writing to request that the Centers for Medicare and Medicaid Services (CMS) investigate the ramifications of KV Pharmaceutical's 150-fold price increase of Makena – a proven progesterone treatment to prevent premature birth – on the Medicaid system.

KV Pharmaceuticals recently obtained exclusive rights to Makena – a FDA-approved drug used to prevent pre-term births – by paying \$200 million to Hologics, Inc, which had conducted the drug's clinical trial. A version of Makena – a progesterone treatment widely available through compounding pharmacies – has been used for decades. For years, women in need of progesterone treatments have been able to purchase the drug for about \$10 an injection – or \$200 a pregnancy. KV Pharmaceuticals stated they will charge \$1,500 an injection – or \$30,000 a pregnancy.

I am concerned about the strain this dramatic price increase will place on Medicaid budgets across the country. According to the American College of Obstetricians and Gynecologists (ACOG), Medicaid finances 42 percent of the nation's more than 4 million annual births. And as approximately 12 percent of all live births involve a preterm baby, I am deeply concerned that the expense of Makena will further burden Medicaid budgets which are already stretched thin.

More alarming still, many women may forgo progesterone treatments due to financial constraints. A baby not carried to full-term is four times more likely to suffer from at least one serious disability – including cerebral palsy, learning disabilities, and behavioral problems. In addition to the life-long health complications that can be caused by pre-term birth, it carries a serious financial burden as well. The health care costs in the first year alone for a premature baby is on average \$51,000; nationally, premature births cost \$26 billion each year.

While I understand the importance of FDA-approved drugs to ensure that medications are safe and effective, KV is taking advantage of FDA's approval of Makena and its orphan drug determination to make enormous profits on the backs of pregnant women, taxpayers, and the Medicaid system.

I urge CMS to evaluate how the drastic price increase of progesterone treatments will affect both Medicaid recipients and Medicaid budgets.

Sincerely,



Sherrod Brown  
United States Senator